ALOE VESTA CLEAR ANTIFUNGAL- miconazole nitrate ointment Convatec Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Aloe Vesta Clear Antifungal Ointment

Drug Facts

Active Ingredient

Miconazole Nitrate 2 percent

Purpose

Antifungal

Uses

- Cures most athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis).
- Relieves itching, scaling, cracking, burning, redness, soreness, irritation, and discomfort that accompany these conditions.
- For treatment of most superficial skin infections caused by yeast (candida albicans).
- Follow a physician's instructions when treating Candida.

Warnings

For external use only.

Do not use on

children under 2 years of age unless directed by a physician.

When using this product,

avoid contact with eyes.

If irritation occurs

or if there is no improvement within 2 weeks for jock itch, or 4 weeks for athlete's foot or ringworm, discontinue use and consult a physician.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Clean the affected area and dry thoroughly.

- Apply a thin layer of ointment over affected area twice daily (morning and night) or as directed by a
 physician.
- Supervise children in use of this product.

For athlete's foot: Pay close attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily. **For athlete's foot and ringworm**, use daily for 4

weeks.

For jock itch: use daily for 2 weeks

- If condition persists longer, consult a physician.
- This product is not effective on the scalp or nails.

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Bis-Diglyceryl Polyacladipate-2, Light Mineral Oil, White Pertolatum

Package label

NDC 43553-0003-2

REF 325102

ALOE VESTA TM

TREAT

CLEAR ANTIFUNGAL

OINTMENT

- CHG Compatible
- Cures Most:
 - -Athlete's Foot
 - -Ringworm
 - -Jock Itch
 - -Superficial Yeast Infections
- Fragrance & Dye Free

with 2 percent Miconazole Nitrate and a Natural Botanical

Net Wt. 2 oz. (56g)

Manufactured for:

ConvaTec

ConvaTec Inc. Skillman, NJ 08558 1-800-422-8811 www.convatec.com

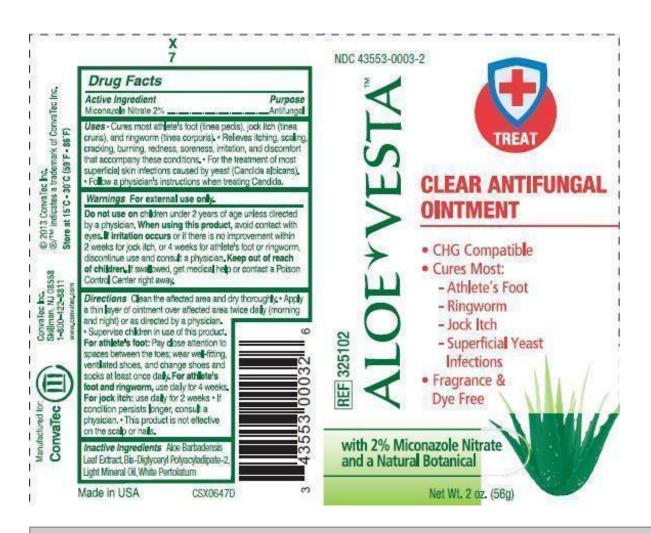
©2013 ConvaTec Inc.

 $\mathbb{R}^{/TM}$ lindicates a trademark of ConvaTec Inc.

Store at 15°C - 30°C (59°F - 86°F)

Made in USA

CSX0647D



ALOE VESTA CLEAR ANTIFUNGAL

miconazole nitrate ointment

Product Information				
	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43553-0003
	Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			

P	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43553-0003-2	56 g in 1 TUBE		

2 NDC:43553-0003-5 141 g in 1 TUBE						
Marketing Information						
Marketing Category	Application Number or Monogra	ph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part333C		12/20/2013			

Labeler - Convatec Inc. (947989757)

Revised: 12/2013 Convatec Inc.